

1/18/2008 Telecon - Seraclone Blood Grouping Reagent Anti-S (Monoclonal)

- Memorandum

Date/Time: January 18, 2008 / 11:35 AM
CBER Najma Khan, CSO, DRB
Representatives:
Biotest' Representative: Pamela J. Vaughan
Subject: Discuss additional information required for submission.
To: File of STNs listed below

Submission Tracking Numbers	Product Proper Names
BL 125219/0	Blood Grouping Reagent, Anti-A (Murine Monoclonal)
BL 125220/0	Blood Grouping Reagent, Anti-B (Murine Monoclonal)
BL 125221/0	Blood Grouping Reagent, Anti-A,B (Murine Monoclonal)
BL 125224/0	Blood Grouping Reagent, Anti-M (Murine Monoclonal)
BL 125225/0	Blood Grouping Reagent, Anti-N (Murine Monoclonal)
BL 125230/0	Blood Grouping Reagent, Anti-K (Monoclonal)
BL 125232/0	Blood Grouping Reagent, Anti-k (Murine Monoclonal)
BL 125233/0	Blood Grouping Reagent, Anti-Le a (Murine Monoclonal)
BL 125213/0	Blood Grouping Reagent, Anti-P 1 (Murine Monoclonal)
BL 125216/0	Blood Grouping Reagent, Anti-S (Monoclonal)
BL 125217/0	Blood Grouping Reagent, Anti-Jkb (Monoclonal)
BL 125222/0	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM)
BL 125223/0	Blood Grouping Reagent, Anti-D (Monoclonal Blend)
BL 125226/0	Blood Grouping Reagent, Anti-C (Monoclonal)
BL 125227/0	Blood Grouping Reagent, Anti-c ((Monoclonal)
BL 125228/0	Blood Grouping Reagent, Anti-E ((Monoclonal)

BL 125229/0	Blood Grouping Reagent, Anti-e ((Monoclonal)
BL 125231/0	Blood Grouping Reagent, Anti-Jka ((Monoclonal)
BL 125207/0	Reagent Red Blood Cells
BL 125215/0	Anti-Human Globulin
BL 125242/0	Anti-Human Globulin (Rabbit/Murine Monoclonal)

Introduction: Biotest AG applied for Biological License Applications (BLAs) for Blood Grouping Reagents and Anti-Human Globulin.

Discussion: The italicized texts are the summary of the sponsor. The following issues were discussed:

FDA received a phone call from Biotest's representative, -----, on January 18, 2008. The italicized texts are the summary of the sponsor's issues. The following issues were discussed:

1. Biotest representative informed FDA that Diagast does not have samples and lot release ready for submission to CBER. Diagast is planning to have an internal meeting to decide when Blood Grouping Reagents lots and Lot Release Protocols will be available, she further stated that it would probably be second week of February 2008.
2. Biotest representative also informed FDA -----

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FDA acknowledged the sponsor's issues

Agreements/Decisions/Action:

Prepared by Najma Khan on January 18, 2008